IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

USA, Plaintiff, v. Xlear Inc., et al., Defendants.	MEMORANDUM DECISION AND ORDER Case No. 2:21-cv-640 RJS DBP Chief Judge Robert J. Shelby Chief Magistrate Judge Dustin B. Pead

Defendants sell various products that contain xylitol, a sugar alcohol, in a variety of over-the-counter saline nasal spray products. During the COVID-19 pandemic Defendants began advertising their saline spray as "capable of preventing and treating COVID-19." Complaint ¶ 2, ECF No. 2. These advertisements claimed Xlear nasal spray offers "up to four hours' of protection, and that '[p]eople should be using Xlear as part of a layered defense to prevent getting COVID-19.'" *Id*. The FTC warned Defendants to stop this line of advertising and eventually filed the instant matter claiming Defendants' deceptive advertising and misrepresentations violated certain sections of the FTC Act, 15 U.S.C. § 45(a), 15 U.S.C. § 52, and the COVID-19 Consumer Protection Act (COVID-19 Act), Pub. L. No. 116-260, Title XIV, § 1401.

Currently before the court are two motions.[1] Defendants move to compel the FDA to produce a Rule 30(b)(6) witness in response to Xlear's subpoena. Specifically, Xlear moves to compel on Topics 1-7, 11, and 17. (ECF No. 94.) Defendants also seek to compel a 30(b)(6) deposition from the FTC, the agency that brought the current matter. Defendants seek answers to

[1] Chief Judge Robert Shelby referred this matter to the undersigned in accordance with 28 U.S.C. § 636(b)(1)(A) to hear and determine all nondispostive pretrial matters. (ECF No. 16.)

certain topics that allegedly address "key issues." Having considered the parties' memoranda and relevant case law, the court enters the following order denying and granting in part the motions.[2]

LEGAL STANDARDS

Federal Rule of Civil Procedure Rule 45 governs the form and issuance of subpoenas at issue here. It operates within the confines of Rule 26.[3] In certain circumstances the court may or must quash a subpoena on a timely motion. The court measures subpoenas against the backdrop of Federal Rule of Civil Procedure 26, which governs discovery disputes. Federal Rule of Civil Procedure 26(b)(1) provides that

> the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.[4]

Discovery at this stage of the litigation is broadly construed.[5] And the court must balance proportionality considerations against the "parties' resources, the importance of discovery in

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[3] *See US Magnesium, LLC v. ATI Titanium LLC*, 2020 WL 12847147, at *5 (D. Utah May 22, 2020) (applying relevancy considerations to subpoena); *Frappied v. Affinity Gaming Black Hawk, LLC* 2018 WL 1899369 *3 (D. Colorado April 20, 2018) ("a subpoena is bound by the same standards that govern discovery between the parties, and, to be enforceable, a subpoena must seek information that is relevant to a party's claims or defenses and proportional to the needs of the case"); *Rice v. United States*, 164 F.R.D. 556, 557 (N.D. Okla. 1995) (finding Rule 45 subpoenas constitute discovery).

[4] F.R.C.P. 26(b)(1).

[5] *See Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) (noting that "any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case" will be deemed relevant).

resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit."[6]

DISCUSSION

I. Defendants' Motion to Compel the FDA to produce a 30(b)(6) witness is denied.

Xlear issued a subpoena to the FDA, who is not a party to this action. Xlear seeks information regarding "whether Xlear's claims are substantiated by competent evidence, including 'evidence based on the expertise of [relevant] professionals'—here, FDA – a leading authority on COVID-19 countermeasures."[7] Specifically, Xlear seeks to compel on Topics 1-7, 11, and 17. These topics deal "directly with FDA's involvement with Xlear or similar nasal sprays."[8] And according to Xlear, it is entitled to testimony regarding the FDA's analysis of the products at issue in this case. Xlear's offers a proposed factual stipulation instead of testimony on Topics 2, 3, and 17. To date, the FDA has declined Xlear's offer. The topics that it seeks to compel 30(b)(6) testimony are:

> 1. The FDA's response to the March 9, 2022 subpoena issued by Xlear (attached as Exhibit A);
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> 2. Any complaint(s) or adverse impact report(s) that the FDA has regarding Xlear nasal spray;
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> 3. The FDA's communications with the Federal Trade Commission ("FTC") regarding Xlear, including but not limited to the telephone conference between the agencies in December 2020;
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> 4. Any interactions between the agency and Dr. Gus Ferrer and Dr. Marcos Sanchez-Gonzalez concerning their COVID-19 research efforts;
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> 5. Any communications, internal or with any third party or parties, the FDA has had concerning Xlear, to include any communications regarding research being

[6] F.R.C.P. 26(b)(1); *see also* Fed. R. Civ. P. 26(b) advisory committee's note to 2015 amendment (seeking to address the explosion of information that has been exacerbated by e-discovery).

[7] Mtn to Compel FDA, ECF No. 94.

[8] *Id.* p. 2.

> considered, conducted, or published regarding the use of Xlear to potentially prevent, ameliorate, treat or otherwise counter the SARS-CoV-2 virus and the resulting COVID-19 disease, to include any and all variants.
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> 6. Any communications, internal or with third parties, regarding nasal-based approaches to potentially prevent, ameliorate, treat or otherwise counter the SARS-CoV-2 virus and the resulting COVID-19 disease, to include any and all variants.
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> 7. Xlear's petition for emergency use authorization ("EUA" and by definition including any "pre-EUA"), and specifically including any communications the FDA had internally or with any external (non-FDA party or parties) concerning Xlear's EUA;
> …
> 11. The FDA real world evidence policies;
> …
> 17. All studies or other research of which the FDA is aware that contradicts or refutes the statement made by Xlear or Mr. Jones of which the FTC is complaining about in this action.[9]

In response to Xlear's motion, the FDA opposes producing a 30(b)(6) witness noting it has already provided 1700 pages of documents to Defendants and "should not be ordered to provide expert witness services to private citizens."[10] The FDA cites to *FTC v. Quincy Bioscience Holding Co., Inc.*,[11] a case out of the Southern District of New York, arguing "'competent and reliable scientific evidence' consists of 'tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.'"[12] Thus, Xlear should seek this competent and reliable scientific evidence and not compel the FDA to become an expert witness for Xlear. The FDA continues, arguing testimony on the requested topics would

[9] Notice of deposition

[10] Op. p. 1, ECF No. 96.

[11] 120 Fed. R. Evid. Serv. 645, 2022 WL 17905783, at *4 (S.D.N.Y. Dec. 19, 2022).

[12] *Id.*

be "irrelevant; duplicative; intrusive upon FDA's deliberative process privilege …, confidential commercial information …, and trade secrets."[13] Further, requiring compliance would be unduly burdensome to the FDA's public health mission.

Before turning to the individual requests, the court notes a roadblock in compelling testimony by FDA employees. Under 21 C.F.R. § 20.1,

> No officer or employee of the Food and Drug Administration …, except as authorized by the Commissioner of Food and Drugs pursuant to this section or in the discharge of his official duties under the laws administered by the Food and Drug Administration, shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information acquired in the discharge of his official duties.[14]

When a subpoena is served upon an officer or employee of the FDA, they may "appear in response thereto and respectfully decline to testify on the grounds that it is prohibited by this section."[15] The case cited to by Xlear for overcoming this prohibition, *Metrex Res. Corp. v. U.S.*,[16] is unpersuasive here. In *Metrex*, the court estopped the EPA from claiming certain researchers were not its employees, and therefore the EPA was not responsible for their attendance at a deposition, after the EPA maintained the plaintiff "could not contact these individuals because they are EPA agents working under EPA contract and could only be approached through EPA counsel."[17] Here, the FDA has made no similar representations, so estoppel is inapplicable.

Setting aside this roadblock to an employee of the FDA testifying, the court agrees with the FDA's arguments concerning the individual requests. For example, topic 2 pertains to the

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[13] Op. p. 2.

[14] 21 C.F.R. § 20.1.

[15] *Id.*

[16] 151 F.R.D. 122 (D.Colo. 1993).

[17] *Id.* at 124-25.

"absence over Xlear's 20-year history of any adverse reports concerning its nasal spray."[18] However, this case focuses on the misrepresentations concerning its nasal spray's effectiveness in treating or preventing COVID-19, it does not focus on the safety of its nasal spray. Thus, Topic 2 is irrelevant.

Topic 3 "requires testimony on communications between FTC and FDA regarding Xlear."[19] Xlear argues this information is available because the deliberative process privilege does not apply. The deliberative process privilege may shield "documents reflecting advisory opinions, recommendations and deliberations compromising part of a process by which governmental decisions and policies are formulated."[20] The privilege is grounded in the "obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news."[21] *Id.* at 8-9. The object of privilege is "to enhance the quality of agency decisions, by protecting open and frank discussion among those who make them within the Government."[22] The privilege applies to information and documents that is "interagency or intra-agency"[23] and some courts have construed intra-agency applicable to documents and communications between Government agencies and outside consultants hired by them.[24] Communications between the FDA and FTC are interagency and the court finds they are

[18] Mtn. p. 2, ECF No. 94.

[19] *Id.*

[20] *Dep't of the Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8, 121 S.Ct. 1060, 149 L.Ed.2d 87 (2001).

[21] *Id.* at 8-9.

[22] *Id*. at 9 (internal citation and quotations omitted).,

[23] *Id.* (citing 5 U.S.C. § 552(b)(5).

[24] *See, e.g., Hoover v. U.S. Dept. of Interior*, 611 F.2d 1132, 1137–1138 (C.A.5 1980); *Lead Industries Assn. v. OSHA*, 610 F.2d 70, 83 (C.A.2 1979); *Soucie v. David*, 448 F.2d 1067 (C.A.D.C.1971).

covered by the deliberative process privilege. Xlear offers no authority for its argument that it is in applicable here.

Topic 4 pertains to the "FDA's interaction with Dr. Ferrer, a physician who conducting COVID-19 research on Xlear."[25] Xlear argues the topic is relevant based on the FTC's subpoena of Dr. Ferrer. The FDA opposes this information asserting Xlear is trying to "conscript FDA into being their expert witness."[26] The court fails to find the relevance here as it is the FTC not the FDA that subpoenaed Dr. Ferrer. Moreover, Xlear can seek discovery directly from Dr. Ferrer regarding the research.

In similar fashion, Topics 5, 6, and 7, seek any communications the FDA had with third parties concerning Xlear including research on Xlear and other nasal-based COVID-19 countermeasures. The court struggles to find the relevance here of FDA communications to others regarding Xlear to the claims in this case. It is the FTC not the FDA that brings this action. Xlear cannot constrict the FDA into being an expert witness on its behalf to undermine the FTC's claims. Moreover, the court is concerned that allowing this information will lead the FDA to disclosing third party confidential commercial information and trade secrets. Such "trade secrets and commercial or financial information"[27] is even exempt from release under FOIA.[28] Finally, the court previously found no need to compel further documentation about other companies' products.[29] Thus, compelling information about other nasal-based COVID-19 countermeasures has already been rejected.

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[25] Mtn. p. 2.

[26] Op. p. 2, ECF No. 96.

[27] 5 U.S.C. § 552(b)(3)(4).

[28] *See Pub. Citizen v. United States Dep't of Health & Hum. Servs.*, 66 F. Supp. 3d 196, 211 (D.D.C. 2014) (finding certain documents that contained confidential commercial information except from release).

[29] Memorandum decision and order dated October 6, 2022, p. 7.

Topic 11 "addresses gaps in FDA's real-world evidence policy"[30] and according to Xlear, they relate to "competent evidence behind Xlear's claims in the emergency environment of COVID-10."[31] The court already found that discovery requests regarding the FDA's issuance of emergency use authorizations is irrelevant to whether "Defendants can substantiate their individual claims about Xlear nasal spray."[32] Testimony about the FDA's emergency use authorization policies is irrelevant.

Topic 17 once again seeks to utilize the FDA as an expert in this case on behalf of Defendants. The court is persuaded that the deliberative process privilege applies here, and this information is not discoverable.

Finally, the FDA provided Defendants declarations authenticating documents and is "unaware of any dispute among the parties as to authenticity."[33] Thus, there is no basis to compel testimony on Topic 1.

For these reasons Xlear's motion to compel 30(b)(6) deposition of the FDA is DENIED. The court is not persuaded that the FDA as a nonparty need designate a 30(b)(6) witness as to the topics sought by Defendants.

[30] Mtn. p. 2.

[31] *Id.*

[32] Memorandum decision and order dated October 6, 2022, p. 6.

[33] Op. p. 3.

II. Defendants motion to compel a 30(b)(6) deposition from the FTC is granted in part.

Defendants move to compel a 30(b)(6) deposition on certain topics from the FTC, the agency that brought the instant case. Defendants seek a witness on Defendants' Topics 5-7, 8-9, and 18, because they are "highly relevant" and "address key issues."[34]

i. Topics 5-7

Topics 5-7 seek:

> 5. FTC's position and policies, including all changes thereto, concerning the standard for substantiating advertising claims related to health under the FTC Act, 15 U.S.C. § 41 et seq, and the COVID-19 Consumer Protection Act from January 1, 2020 to the present. This topic includes but is not limited to the amount, type, and/or quality of evidence required to satisfy the substantiation standard, and the circumstances under which health product companies may satisfy the standard.
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> 6. FTC's 2022 Guidance Publication and its application to statements, representations, or claims made by companies marketing health products. This topic includes but is not limited to the principles, methodologies, and information in the 2022 Guidance Publication, the application of that information to any allegedly false, misleading, or unsubstantiated claims made by Defendants, and the differences between the 2022 Guidance Publication and 1998 Guidance Publication.
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> 7. FTC's 1998 Guidance Publication and its application to the statements, representations, or claims made by companies marketing health products or dietary supplements. This topic includes but is not limited to the principles, methodologies, and information in the 1998 Guidance Publication, the application of that information to any allegedly false, misleading, or unsubstantiated claims made by Defendants, and the differences between the 1998 Guidance Publication and 2022 Guidance Publication.[35]

Defendants state that these topics "bear directly on the critical element of whether competent and reliable scientific evidence supports Defendants' advertisements."[36] The FTC

[34] Mtn. p. 1, ECF No. 103.

[35] Pla.'s Op Ex 1 (ECF No. 105-1).

[36] Mtn. p. 2.

argues its guidance is not at issue here because the FTC has not alleged that Defendants failed to comply with guidance. Accordingly, the topics are irrelevant, overbroad, and unduly burdensome.

Plaintiff's complaint focuses on the allegations that "Defendants lacked valid factual or scientific bases" for their COVID-19 claims regarding their products, and Defendants engaged in "deceptive advertising and misinformation" to sell their products.[37] Topic 5 regarding the standards for substantiating advertising claims is relevant and is not overbroad or unduly burdensome as it has a time limitation. Topics 6 and 7, however, focus on guidance publications. A failure to follow guidance is not alleged in the Complaint. Moreover, the court agrees that the guidance publications speak for themselves and 30(b)(6) testimony about the FTC's legal theories are not a proper basis for 30(b)(6) testimony.[38] Thus, the FTC need not prepare someone on Topics 6 and 7, but Topic 5 is proper.

ii. Topics 8-9

Topics 8 and 9 request:

> 8. The circumstances surrounding and reasons underlying FTC's recently published "Notice of Penalty Offenses Concerning Substantiation of Product Claims."
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> 9. The circumstances surrounding and reasons underlying FTC's Division of Advertising Practices, mass mailing or other delivery of Notices of Penalty Offenses on or about April 13, 2023 to companies FTC asserts are making health claims.[39]

[37] Complaint p. 2.

[38] *See Ward v. Nesibo*, No. 4:22-CV-00054-DN-PK, 2023 WL 3391145, at *4 (D. Utah May 11, 2023) (finding deposition testimony regarding legal theories in appropriate); *JPMorgan Chase Bank v. Liberty Mut. Ins. Co*., 209 F.R.D. 361, 362 (S.D.N.Y. 2002) ("In a nutshell, depositions, including 30(b)(6) depositions, are designed to discover facts, not contentions or legal theories, which, to the extent discoverable at all prior to trial, must be discovered by other means.").

[39] Pla.'s Op Ex 1 (ECF No. 105-1).

Defendants state that these requests focus on how the FTC provides notice when seeking penalties, whether Defendants received such notice, the FTC's "mass transmission of 670 warning letters to health-product advertisers", any FTC decision concluding Defendants' alleged conduct is deceptive, and how Defendants knew their conduct was deceptive.[40] Thus, they are relevant to the instant matter.

Plaintiff seeks to draw a distinction between the information that Defendants request and the claims brought in the Complaint. Plaintiff states that the Complaint seeks civil penalties under 15 § U.S.C. §45(m)(1)(A), and not 15 U.S.C. §45(m)(1)(B), which makes the notices irrelevant. Plaintiffs point to paragraphs 17 and 55 that cite to §45(m)(1)(A).[41] Paragraph 55 is the beginning of Plaintiff's prayer for relief and it specifically seeks relief pursuant to "Sections 5(a)(1), 5(m)(1)(A), 13(b), and 19 of the FTC Act, 15 U.S.C. §§ 45(a)(1), 45(m)(1)(A), 53(b), and 57b, Section 1401(c)(2)(A) of the COVID-19 Consumer Protection Act, and the Court's own equitable powers…."[42]

The court agrees with Plaintiff's position that there are differences between these sections based on their plain language. Section (m)(1)(A) provides that the FTC may "commence a civil action to recover a civil penalty in a district court of the United States against any person, partnership, or corporation which violates any rule under this subchapter respecting unfair or deceptive acts or practices …"[43] Section (m)(1)(B) provides that if the FTC " determines in a proceeding under subsection (b) that any act or practice is unfair or deceptive," then the FTC

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[40] Mtn. p. 3.

[41] Paragraph 17 states: "A violation of Section (b)(1) of the COVID-19 Consumer Protection Act made with the knowledge required by Section 5(m)(1)(A) of the FTC Act, 15 U.S.C. § 45(m)(1)(A), is subject to monetary civil penalties of up to $43,792 for each violation of the COVID-19 Consumer Protection Act after January 13, 2021, including penalties whose associated violation predated January 13, 2021." Complaint ¶17, ECF No. 2.

[42] Complaint ¶55, ECF No. 2.

[43] 15 U.S.C. §45(m)(1)(A).

may commence a civil action to obtain a civil penalty.[44] The Complaint does not cite to nor reference §45(m)(1)(B).

The COVID-19 Consumer Protection Act (CCPA) was enacted in December 2020 and it prohibits "any person, partnership, or corporation to engage in a deceptive act or practice in or affecting commerce in violation of section 5(a) of the [FTC] Act (15 U.S.C. 45(a)) that is associated with the treatment, cure, prevention, mitigation, or diagnosis of COVID-19[.]" Public Law 116-260, 134 Stat 1182, Title XIV, Section 1401(b)(1). The CCPA is enforced by the FTC.[45] The premise for the FTC enforcing the CCPA is different under §(m)(1)(A) and §(m)(1)(B). Therefore, there is no need to prepare a witness as to these topics.

iii. Topic 18

Topic 18 seeks "routine examination on FTC's discovery responses."[46] Topic 18 states: "Plaintiff's responses to Defendants requests for admission, interrogatories, and requests for production of documents."[47] Defendants argue a response is not unduly burdensome here because they "agreed to limit testimony to specific, reasonable number of their 80 RFAs."[48] According to Defendants, it is a regular common practice to follow upon written discovery at a deposition.[49]

In contrast, Plaintiff objects to this "discovery on discovery" and argues Rule 30(b)(6)'s requirement of reasonable particularity is not met when a topic requires a party to prepare a

[44] 15 U.S.C.§ 45(m)(1)(B).

[45] *Id.* at §1401(c).

[46] Mtn. p. 3.

[47] Pl.'s Op. Ex. 1 p. 14-15.

[48] Mtn. p. 3.

[49] Citing to *Corker v. Costco Wholesale Corp.*, No. C19-0290RSL, 2021 WL 84471, at *2 (W.D. Wash. Jan. 11, 2021).

designee to testify about "'every aspect of nearly all claims made … and discuss every document [the party] produced.'"[50] Plaintiff cites to *Bizzaro v. First American Title Co. LLC*,[51] a decision from this court arguing Defendants have not provided reasonable particularity.

The court is not persuaded by Plaintiff's position. In *Bizzaro*, the requested topics were much more generalized than those here. The plaintiff there sought testimony regarding allegations set forth in the amended complaint, counterclaim, third-party complaint, defenses asserted, and the documents produced in connection with the case. Here, Defendants have agreed to limit it in a more particular fashion. Thus, testimony is not required about every aspect of nearly all claims made and all documents produced, and a 30(b)(6) witness is to be designated as to Topic 18.

ORDER

Based upon the foregoing, the court:

DENIES Defendants' Motion to Compel Deposition of FDA on certain topics and

GRANTS IN PART AND DENIES IN PART Defendants' Motion to Compel the FTC to produce a 30(b)(6) witness on certain topics.

IT IS SO ORDERED.

DATED this 18 September 2023.

Dustin B. Pead
United States Magistrate Judge

[50] Pl.'s Op. p. 3, ECF No. 105 (quoting *Bizzaro v. First Am. Title Co. LLC,* 2:15-cv-320, 2016 WL 2939146, at *3 (D. Utah May 19, 2016)).

[51] 2016 WL 2939146.